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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,028	09/18/2000	Sydney M. Pugh	3477/133(2015	4345
826	7590	07/15/2004	EXAMINER	
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			BERKO, RETFORD O	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,028

Applicant(s)

PUGH ET AL.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 53-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 57 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/29/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement: Receipt of Status Inquiry Request filed February 17, 2004; Receipt of Amendment filed July 22, 2002; Receipt of Information Disclosure Statement filed January 08 and Receipt of fax transmission dated June 29, 2004 is hereby acknowledged.

Status of Claims

- a. Claim 1 is pending in view of applicant's amendment.
- b. Claims 2-37 are cancelled in view of the amendment.
- c. Claims 38-52 are withdrawn from consideration (Disposition of Claims, Office Action mailed 12/12/02 in Paper No. 10).
- d. Claims 53-57 are pending in view of amendment. Examiner called Attorney Scott Young to verify this issue as claims 54-57.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 is rejected as unpatentable under 35 U.S.C. 103(a) over Chow et al (US 5, 695, 729) in view of Gerhart et al (US 4, 843, 112) further in view of Sander et al (US 5, 356, 629).
3. Claim 1 is directed toward a biomaterial comprising a bioresorbable biomaterial comprising calcium, oxygen and phosphorus, wherein a portion of at least one of the elements is substituted with an element having an ionic radius of 0.1-0.6 Angstrom and a pharmaceutical agent.

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4. Chow et al (Patent '729) discloses a bone cement composition comprising hydroxyapatite and tetracalcium phosphate (average particle size of less than 15 microns) possessing improved mechanical strength properties and easy to mold into desired contours; said bone cement is biocompatible and sets at ambient temperature and therefore easy to use (abstract, col 5, lin 5-25 and col 16, lin 21-25). Thus Patent '729 also discloses a composition comprising calcium, oxygen and phosphorus that is bioresorbable (col 3, lin 46-48)

5. Patent does not disclose ionic radius (i.e. size of particles or size of the constituent elements within the matrix) and does not disclose a drug in the composition.

6. Gerhart et al (Patent '112) discloses particulate resorbable composition comprising calcium phosphate and hydroxyapatite dispersed in biodegradable polyester (abstract, col 5, lin 20-30 and col 14, lin 25-35). Patent '112 discloses an embodiment of the invention in the form as bone cement comprising autograft or allograft bone particles and that the composition is implantable and can induce bone growth in surgical applications (col 4, lin 25-30; col 6, lin 50-55 and col 7, lin 6-35). More importantly, Patent '112 discloses an embodiment of the composition that comprises drugs such as antibiotics for sustained drug delivery to sites where the composition is implanted (col 3, lin 55; col 4, lin 5-10 and col 11, lin 55-60).

7. Sander et al (Patent '629) discloses a composition suitable for bone repair comprising biocompatible particles dispersed in a matrix than can be implanted into defective bone tissue (abstract, col 2, lin 35-40, col 3, lin 50-55 and col 5, lin 35-40). Patent '629 discloses the use of drugs and other substances that can induce bone growth in the composition (col 4, lin 55-65; continuing to col 5, lin 1-15). More significantly, Patent '629 discloses that the biocompatible

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particles of any size may be used in the composition and that matrix material can be conveniently comminuted to the appropriate particle size of mixing (col 4, lin 30-39 and col 35-40).

8. One of ordinary skill in the art would be motivated to prepare a composition comprising calcium phosphate and other ingredients (thus using a compound comprising calcium, oxygen and phosphorus), pharmaceutical agents and bone inducing growth factors to form a bone cement composition as disclosed in the prior art cited. By substituting elements having ionic radii that is convenient, thereby control the particle size in the composition forming the bone cement matrix, one of ordinary skill would expect to obtain a composition that can be molded and implanted into a bone defective site in order to induce bone growth and repair while preventing or mitigating the possibility of infection at the injured site due to the antibiotic action of the drugs incorporated into the composition. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

10. Claims 1 and 53-57 are rejected under 35 U.S.C. 103(a) as unpatentable over Chow et al (US 5, 695, 729) in view of the combination of Gerhart et al (US 4, 843, 112), Sander et al (US 5, 356, 629) and Kasuga et al (US 5, 232, 878).

11. The claims are directed toward a biomaterial comprising a bioresorbable biomaterial comprising calcium, oxygen and phosphorus, wherein a portion of at least one of the elements is substituted with an element having an ionic radius of 0.1-0.6 Angstrom and a pharmaceutical agent. The claims are also directed toward slow release of the drug incorporated in the composition, and the composition comprises a bone growth factor. The claims are further drawn toward the composition comprising a compound wherein the elements of the compound are

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calcium, phosphorus, oxygen, silicon or boron---the presence of silicon or boron alters the valency of the elemental phosphorus in the compound thus formed accordingly.

12. The disclosures of Chow et al (Patent '729), Gerhart et al (Patent '112), Sander et al (Patent '629) have been discussed above (paragraphs 4-7). None of the Patents disclose the use of boron in forming a biomaterial composition.

13. Kasuga et al (Patent '878) discloses a process for producing stabilized biocompatible inorganic biomaterials comprising compounds such as calcium phosphate, calcium oxide, phosphorus pentoxide, silicon dioxide, magnesium oxide and aluminium oxide (abstract, col 21, lin 1-10). Patent '878 discloses that the inorganic biomaterial is useful as biomaterial for artificial bones, dental implants etc (abstract). More importantly, Patent '878 discloses that the biomaterial can optionally contain, in addition to the elements or compounds used in the invention; at least one component selected from a group of compounds including boron oxide (col 5, lin 10-25).


14. One of ordinary skill in the art would be motivated to prepare an inorganic biomaterial that is biocompatible and make a composition comprising calcium phosphate and other ingredients (thus using a compound comprising calcium, oxygen and phosphorus), pharmaceutical agents and bone inducing growth factors. By optionally adding boron oxide to the composition, one of ordinary skill would expect to obtain a bone repair composition that can be molded and implanted into a bone defective site in order to induce bone growth and repair while preventing or mitigating the possibility of infection at the injured site due to the controlled release of antibiotic drugs incorporated into the composition. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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